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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

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DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/662,790

Applicant(s)

CHANDLER ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Applicants' arguments, filed 12 May 2003, have been fully considered by they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-7 and 39 are currently pending in the application.

Newly submitted claim 39 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 39 is drawn to a method of using a Multi-Analyte Profile. The invention of claims 1-7 and the invention of claim 39 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the Mutli-Analyte Profile could be used in a different process, such as a process for assessing compound interactions for drug development.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 39 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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Claims Objections

Claim 7 remains objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 1 and 7 are directed to the same Test Panel. The insertion of "kit" in the preamble does not change the structural or functional limitations of these claims. Applicant argues that kits may be prepared comprising MAP Test Panel and associated buffers however these limitations are not recited in the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7, and 8 of U.S. Patent No. 6,524,793 B1 in view of WO 99/19515 (22 April 1999-PTO Form 1449).

US 6,524,793 B1 claims:

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1. A particle set for flow analysis comprising a pooled population of subsets of particles having the same size, the particles in each subset having (i) at least one **characteristic classification parameter that distinguishes particles of one subset from those of another subset**, the at least one characteristic classification parameter **including at least one fluorescence emission intensity**, (ii) a reactant **specific for an analyte of interest**, and (iii) a reactant surface-density specific for each subset of particles, wherein at least two subsets of particles are distinguishable from each other by their reactant surface-density.

2. The particle set according to claim 1, wherein said pooled population includes a **plurality of subsets** of particles per reactant.

3. The particle set according to claim 1, wherein said at least one characteristic classification parameter includes **two distinct fluorescence emission intensities**.

7. The particle set according to claim 1, wherein said **analyte of interest includes antigens, antibodies, peptides, proteins, nucleic acids, or enzymes**.

8. The particle set according to claim 1, wherein said **reactant includes a tracer antigen or antibody, a synthetic oligonucleotide, or a capture probe**.

While the specific species of the genus' are not mentioned in the claim language, WO 99/19515 teaches a population of subsets of dyed beads in batches, each one of them having a predetermined ratio or proportion of **two or more fluorescent dyes** (page 4, line 14-15). The set, having optically distinct microspheres is useful for simultaneous analysis of a plurality of analytes in the same sample. The reagents and analytes can comprise a myriad of substances, including antibodies and antigens (page 19, example 3).

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WO 99/19515 also states: “ due to a significant improvement over existing methodology is now technically possible to obtain **16-subset, 32-subset, 64-subset or even higher number** of bead collections using the instant methodology”. Furthermore, a series of analytical reagents could be employed, as in example 3. Thus, it would have been prima facie obvious to one of ordinary skill in the art to incorporate the specific numbers from WO 99/19515 into the meaning of the claims of the instant invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, as stated in the Previous Office Action, the provisional application upon which priority is claimed **fails** to provide adequate support under 35 U.S.C. 112 for claims 1-7 of this application. Claims 1-7 are drawn to a Multi-Analyte Profile Test Panel. The provisional application 60/153,941, while mentioning the MAP Test Panel, does not provide a detailed description of the Panel such that one could use or make it. Instead, the provisional application is drawn to a computer database for diagnosis. Therefore, the instant filing date of 15 September 2000 is used to assess appropriate prior art under 35 USC 102. Applicant argues that the provisional application, 60/153,941, does provide adequate written description to support the MAP Test Panel of the present invention. Applicants support for this argument points to page 5, last full paragraph, which “incorporates the necessary teaching by reference to several published PCT patent

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applications; WO 99/19515, which is alleged in the present Office Action to be 35 U.S.C. 102(b) reference against the present application, is among these.” However, this is not persuasive for the following reason: Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found.

Claims 1, 3, and 4-6, therefore, remain rejected under 35 U.S.C. 102(b) as being anticipated by Kettman et al. (Cytometry 1998, Vol.33, pages 234-243).

Kettman et al. teach a method and system for analysis of multiple analytes in a single sample. (see abstract, page 234):

“The vehicle for each separate measurement consists of a set of microspheres identifiable by characteristic fluorophores embedded in the particles. The use of robust bench-top flow cytometers for the analysis of the multiple sets of microspheres is facilitated by hardware and software, which acquire the data from cytometer, classify the microspheres according to sets, and collate measurement information for each set of microspheres in real time. This measurement system can analyze up to 64 analytes in a single sample”.

Kettman et al. therefore meet the limitations of claims 1, 3, and 4-6.

Claims 1-7 are also rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/19515 (22 April 1999-PTO Form 1449).

WO 99/19515 teaches a population of subsets of dyed beads in batches, each one of them having a predetermined ratio or proportion of two or more fluorescent dyes (page 4, line 14-15).

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The set, having optically distinct microspheres is useful for simultaneous analysis of a plurality of analytes in the same sample. The reagents and analytes can comprise a myriad of substances, including antibodies and antigens (page 19, example 3).

WO 99/19515 also states: " due to a significant improvement over existing methodology is now technically possible to obtain 16-subset, 32-subset, 64-subset or even higher number of bead collections using the instant methodology". Furthermore, a series of analytical reagents could be employed, as in example 3.

Applicant argues again that WO 99/19515 is not a proper 102(b) reference. However, the priority to 60/153,941 is denied and therefore, WO 99/19515 published 22 April 1999 is a proper 102(b) reference.

Claims 1, 2, and 5-7 are also rejected under 35 U.S.C. 102(b) as being anticipated by Kettman et al. (Cytometry (1998) October, Vol. 33, pages 234-243).

Kettman et al. teach a method for the analysis of multiple analytes in a single sample in which the vehicle for each separate measurement consists of a set of microspheres identifiable by their characteristic fluorophores embedded in the particles (abstract, column 1). Kettman et al. describe the design and construction of the FlowMetrix™ microspheres on page 325, column 2. Specifically, the molecules attached to the microsphere surface are called the "target" molecules and consist of two fluorescent dyes (orange and red). The labeled molecules that bind the microsphere are called the "reporter" (green). In this paper, a set of 64 microspheres were analyzed, thus meeting the limitations of claim 1, 2, and 7. Furthermore, Kettmann et al. describe that these panels are useful for analysis of antibodies, antigens, and other s

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molecules, including nucleic acids, drugs, and enzymes (see introduction), meeting the limitations of claim 5 and 6.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 28, 2003

Lori A. Clow, Ph.D.

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Lori A. Clow